IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MEDTRONIC, INC., *Plaintiff*, v. BIOGEN MA INC., *Defendant.*	Case No. 1:23-cv-10057-VSB

BIOGEN MA INC.'S MEMORANDUM OF LAW
IN SUPPORT OF ITS MOTION TO DISMISS

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Defendant Biogen MA Inc. ("Biogen"), by and through its counsel, submits this memorandum of law in support of its Motion to Dismiss the Complaint filed by Medtronic, Inc. ("Medtronic").[1]

PRELIMINARY STATEMENT

By this action, Medtronic seeks to collect more than it bargained for in connection with a now-terminated Development and Commercialization Agreement (the "Agreement"). The present dispute rests entirely on the parties' disagreement on proper legal interpretation of a few contractual provisions. The Court should dismiss the Complaint now based on the clear and unambiguous language of the Agreement which renders Medtronic's claims untenable in view of its own factual concessions.

The Agreement at issue governed the parties' collaboration to develop and market a drug delivery system to treat spinal muscular atrophy ("SMA"). It contemplates three distinct stages of activity: a "pre-clinical" stage including clinical development and regulatory work leading to filing an investigational device exemption ("IDE") to enable clinical trials (the "Pre-Clinical Stage"); a "clinical" stage in which clinical trials would be run with the goal of generating sufficient data to support regulatory approval to market the product (the "Clinical Stage"); and finally, commercialization. The Agreement requires Biogen to pay Medtronic certain amounts for achievement of milestones, and additional invoiced amounts for clinical and regulatory work but only in accordance with the budget for those activities in the approved development plan.

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[1] Citations to specific paragraphs of the Complaint filed on November 15, 2023 (ECF No. 1) are denoted herein as "Compl. ¶ _." Citations to the "Agreement" refer to Exhibit A (Development and Commercialization Agreement) annexed to the Declaration of Olga L. Fuentes-Skinner, dated December 11, 2023. Internal citations and quotations are omitted throughout unless otherwise indicated.

After paying Medtronic far more than the [redacted] minimum due for such work in the Pre-Clinical Stage, and far more than the total budgeted amount for non-milestone payments in the Pre-Clinical Stage, Biogen exercised its termination rights before the collaboration reached clinical trials.

In its Complaint, Medtronic concedes two critical facts: Biogen properly terminated the Agreement before the collaboration reached the Clinical Stage; and Biogen paid Medtronic [redacted] in milestone payments, and additional amounts exceeding the [redacted] in separately budgeted clinical and regulatory work non-milestone payments set forth in the approved development plan. Medtronic nonetheless asserts two grounds for breach of contract based on its misinterpretation of the clear language in the Agreement.

First, Medtronic claims entitlement to an additional [redacted], citing a provision that ensures at least [redacted] will be paid to Medtronic "pursuant to Section 6.1" (the section governing Biogen's payment obligations in the Pre-Clinical Stage). Medtronic acknowledges that Biogen paid [redacted] in milestones pursuant to Section 6.1. Medtronic also concedes that Biogen paid over [redacted] more to Medtronic under the Agreement (the budgeted non-milestone payments for clinical and regulatory work during the Pre-Clinical Stage). To ground its claim, Medtronic argues that Biogen's non-milestone payments were paid not pursuant to Section 6.1, but pursuant to Section 6.2 (which governs Biogen's payment obligations for the Clinical Stage). As the parties never even filed an IDE to enable clinical trials, this argument must fail.

Medtronic's second argument fares no better. There, Medtronic seeks payment of [redacted] in invoices which are not supported by the approved development plan budget. In fact, Medtronic concedes in its Complaint that Biogen paid all such amounts long ago, given

Medtronic's rapid overspend during the collaboration. The Agreement explicitly conditions Biogen's payment obligations on invoiced work being in accord with the development plan budget. Medtronic ignores this express condition on Biogen's payment obligation, and instead attempts to rely on course of conduct and waiver – both of which are explicitly prohibited by the terms of the Agreement. Biogen has paid Medtronic all it was owed under the Agreement. Medtronic got far more than the guaranteed [redacted] for work in the Pre-Clinical Stage, overspent its approved budgets, and asks this Court now to rewrite the terms of the Agreement to give it more than it contracted to receive. The Court should dismiss the Complaint with prejudice.

FACTUAL BACKGROUND[2]

A. Provisions Governing The Pre-Clinical Stage

Sections 3.1 and 6.1 of the Agreement, and Workplan 1(a) in Exhibit A thereto, concern the Pre-Clinical Stage of product development. "Development" is defined broadly in Section 1.27 to include "all internal and external research, development, clinical and regulatory activities related to drugs or medical devices…"[3] Article 3 of the Agreement describes the different stages of "Development" activities the collaboration would involve.

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[2] Unless otherwise indicated, the facts described below are as alleged in the Complaint and are accepted as true for purposes of this motion only. The facts are also drawn from the Agreement, which is incorporated by reference in the Complaint.

[3] Section 1.27 defines "Development" to include:

> all internal and external research, development, clinical and regulatory activities related to drugs or medical devices, including (a) research, non-clinical testing, toxicology, testing and studies, non-clinical and preclinical activities and (b) preparation, submission, review and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support or maintain Regulatory Approval of a drug or medical device and interacting with Regulatory Authorities in the applicable country or region for such product or device regarding the foregoing (whether prior to or after receipt

Section 3.1 describes pre-clinical Development activities:

> 3.1. Pre-Clinical Development. The Development Plan shall set forth all of the pre-clinical Development activities to be performed in connection with this Agreement, with the goal of all such pre-clinical Development activities being the generation of data and information with respect to the Port Kit and Access Kit sufficient to support Regulatory Filings [the IDE] required by Regulatory Authorities as a prerequisite to commencing Clinical Trials of the Port Kit and Access Kit.

Agreement at 11 (emphasis added). By its clear and unambiguous terms, Section 3.1 governs the Development work done *prior* to the commencement of clinical trials.

The "Development Plan" referenced in Section 3.1 is attached to the Agreement as Exhibit A, and describes discrete "workplans." *Id.* at 45. Workplan 1(a) – titled "Kickoff to IDE Approval" – governs the Pre-Clinical Stage, listing three goals: "(1) Design and Development of Port Kit & Access Kit;" "(2) Clinical and regulatory activities for IDE submission;" and (3) "IDE submission for the commencement of a clinical trial for the purposes of securing regulatory approval from the FDA." *Id.* at 45-49. It also includes budgeted milestone payments, as well as budgeted amounts for clinical activities [redacted] and regulatory activities [redacted] for the Pre-Clinical Stage. *Id.* at 46-49.

Article 6 of the Agreement contains the "Financial Terms" of the contract. Section 6.1 sets forth Biogen's obligations to fund the pre-clinical Development activities described in Section 3.1:

> 6.1. Payments for Pre-Clinical Development. In consideration of Medtronic conducting pre-clinical Development activities pursuant to Section 3.1 (including, if applicable, for any additional pre-clinical Development activities described in Section 3.3), Biogen will pay Medtronic in accordance with the budget for such activities as set forth in the Development Plan, with such pre-clinical Development payments, in the aggregate, equaling [redacted] as of the Effective Date. With respect to pre-clinical Development activities, Medtronic will

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> of Regulatory Approval), but excluding activities expressly described in the definitions of Manufacturing or Commercialization.

Agreement at 4 (emphasis added).

> invoice Biogen (but not more than once per month) for such pre-clinical Development activities within thirty (30) days of completing the "Phase" (as set forth in Workplan 1 (a) of the Development Plan) of Development for such pre-clinical Development activities.

Id. at 19 (emphasis added). By its clear and unambiguous terms, Section 6.1 requires payment for work performed under Section 3.1. Biogen's payment obligation is also conditioned on invoiced amounts being "in accordance with the budget for such activities as set forth in the Development Plan." *Id.* And, appropriately, Section 6.1 specifically references Workplan 1(a) which contains such budgets, as noted above.

B. Provisions Governing The Clinical Stage

By contrast, Sections 3.2 and 6.2 concern the Clinical Stage of work which follows the Pre-Clinical Stage. *Id.* at 11, 19. The Clinical Stage is that in which clinical trials are run when the parties receive regulatory approval to do so after filing of an IDE. Section 3.2 describes this separate stage of clinical and regulatory Development activities aimed to generate data to support regulatory approval to market and commercialize the product:

> 3.2 Clinical Development and Regulatory Responsibilities.
>
> 3.2.1 Clinical Development. The Development Plan shall set forth all of the clinical Development activities (including all Clinical Trials) to be performed in connection with this Agreement, with the goal of all such clinical Development activities being the generation of sufficient data and information with respect to the Port Kit and Access Kit to support Regulatory Filings required by Regulatory Authorities to obtain Regulatory Approval to Commercialize the Port Kit and Access Kit for use in connection with Drugs in the Territory.
>
> 3.2.2 Regulatory Activities. The Development Plan shall also set forth all of the regulatory Development activities to be performed in connection with this Agreement, with the goal of all such regulatory Development activities being the submission of Regulatory Filings required by Regulatory Authorities to obtain Regulatory Approval to Commercialize the Port Kit and Access Kit for use in connection with Drugs in the Territory. …

Id. at 11 (emphasis added).

Just as Section 6.1 provides financial terms for the Pre-Clinical Stage described in Section 3.1, Section 6.2 dictates Biogen's funding obligations for the Clinical Stage described in Section 3.2:

> 6.2. Payments for Clinical and Regulatory Development Activities. In consideration of Medtronic (a) conducting clinical Development activities pursuant to Section 3.2.1, (b) conducting regulatory Development activities pursuant to Section 3.2.2(a) and (c) conducting any agreed-on additional clinical or regulatory Development activities pursuant to Section 3.3, with respect to (a)-(c), Biogen will pay Medtronic, in accordance with the budget for such activities as set forth in the Development Plan, for the FTE Costs and actual and documented out-of-pocket expenses incurred by Medtronic in connection with undertaking such activities. Medtronic will invoice Biogen for such costs monthly. For clarity, amounts payable under this Section 6.2 may include agreed-on amounts payable for post-Commercialization clinical or regulatory Development activities that are provided for in the Commercialization Plan rather than the Development Plan.

Id. at 19 (emphasis added). Here, too, Biogen's obligations are limited to amounts budgeted in the Development Plan. Workplan 1(b) within the Development Plan describes the clinical work done in the Clinical Stage, with the goal of "[e]xecution of a Clinical Trial to generate Sufficient data and information with respect to the Port Kit & Access Kit to support regulatory filing required for regulatory approvals (FDA / CE Mark)." *Id.* at 45. Workplan 1(c) describes the regulatory submissions to follow such clinical trials.

C. Biogen's Payments To Medtronic And Termination

Biogen paid Medtronic [redacted] in milestone payments pursuant to Section 6.1. Compl. ¶ 16. Biogen further paid Medtronic at least [redacted] in additional invoiced amounts for the budgeted clinical and regulatory work in Workplan 1(a), for a total of at least [redacted]. Compl. ¶18 (Biogen paid Medtronic in excess of [redacted]), *id.* ¶ 19 (Biogen paid Medtronic more than [redacted]), *id.* ¶ 38 (Medtronic exceeded the budget in Workplan 1(a) for Clinical Activities and Regulatory Activities), *id.* ¶ 39 (Biogen continued to pay Medtronic's invoices after Medtronic had exceeded the budget for those activities), *id.* ¶ 40 (Biogen paid for

the work Medtronic performed), *id.* ¶ 44 (Medtronic had exceeded the budget for Workplan 1(a) and Biogen paid Medtronic for its work). In point of fact, Biogen paid Medtronic over [redacted] for work done pursuant to the Agreement, but for purposes of the present motion, Medtronic's concessions in its Complaint suffice.

Biogen terminated the Agreement for convenience on April 14, 2022, prior to submission of an IDE, as was its right under Section 11.3. *Id.* ¶¶ 3, 25. Upon termination for convenience, Biogen was required to ensure that Medtronic would receive an aggregate total of [redacted] for pre-clinical activities pursuant to Section 6.1:

> 11.6.4 Existing Obligations. Neither Party shall be relieved of any obligation that accrued prior to the effective date of expiration or termination and, in addition:
>
> (a) in the event Biogen terminates this Agreement pursuant to Section 11.3 prior to completion of the Development Plan, within forty-five (45) days of the effective date of termination, Biogen will make a single payment to Medtronic so that Medtronic receives, in the aggregate, [redacted] (or, if increased due to additional pre-clinical Development activities added to this Agreement pursuant to Section 3.3, such amount as provided for in the Development Plan as of the effective date of termination) pursuant to Section 6.1. For example, if, in connection with Medtronic conducting pre-clinical Development activities, Biogen made [redacted] in payments to Medtronic pursuant to Section 6.1 prior to the effective date of termination, then Biogen would make an additional payment to Medtronic of [redacted].

Agreement at 35 (emphasis added).

As set out above, the activities compensated "pursuant to Section 6.1" are the activities set out in Section 3.1 – pre-clinical development, clinical and regulatory activities compensated by milestones and invoiced amounts in accordance with the budget detailed in Workplan 1(a). Section 11.6.4 does not say that Medtronic is entitled to [redacted] in milestone payments under Section 6.1, but rather that the total amount paid "pursuant to Section 6.1" would be at least [redacted]

[redacted]. As detailed above, by Medtronic's own admissions, Biogen paid over [redacted] to Medtronic for its work in the Pre-Clinical Stage. Compl. ¶ 18.

D. Non-waiver/No Oral Modification Provisions

The Agreement also contains robust clauses preventing amendment or waiver without written documentation. Section 14.8 states that "[a]ny term of this Agreement may be amended only with the written consent of Biogen and Medtronic." Agreement at 41. Similarly, Section 14.10 directly addresses waivers, stating:

> No delay or omission to exercise any right, power, or remedy accruing to any Party upon any breach or default under this Agreement, shall be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent, or approval of any kind or character on the part of any Party of any breach or default under this Agreement, or any waiver on the part of any Party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement or by law or otherwise afforded to any of the Parties, shall be cumulative and not alternative.

Id. at 42 (emphasis added).

Medtronic does not allege that Biogen ever agreed in writing to amend the terms of the Agreement as set forth above, nor to waive any rights or obligations in the Agreement.

LEGAL STANDARDS

To survive a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure, "a complaint must contain sufficient factual matter . . . to state a claim [] that is plausible on its face." *Off. Sol. Grp., LLC v. Nat'l Fire Ins. Co. of Hartford*, 544 F. Supp. 3d 405, 412 (S.D.N.Y. 2021). While the Court "must accept as true all of the allegations contained in a complaint," this "tenet . . . is inapplicable to legal conclusions," and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). On a motion to dismiss, the Court "need not accept

conclusory allegations or legal conclusions couched as factual [] allegations." *Milan v. Wertheimer*, 808 F.3d 961, 963 (2d Cir. 2015).

Dismissal is appropriate where the allegations, if accepted as true, do not establish "an actual breach of the contract." *Ace Arts, LLC v. Sony/ATV Music Pub., LLC*, 56 F. Supp. 3d 436, 451 (S.D.N.Y. 2014). "Under New York law, a breach of contract claim requires proof of: "(1) an agreement, (2) adequate performance by the plaintiff, (3) breach by the defendant, and (4) damages." *Fischer & Mandell, LLP v. Citibank, N.A.*, 632 F.3d 793, 799 (2d Cir. 2011).

In deciding a motion to dismiss, the Court may consider documents attached to the complaint as an exhibit or incorporated in the complaint by reference. *See, e.g., ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007)*; Rothman v. Gregor*, 220 F.3d 81, 88 (2d Cir. 2000) ("For purposes of a motion to dismiss, we have deemed a complaint to include any written instrument attached to it as an exhibit or any statements or documents incorporated in it by reference . . . ."). Critically, "[a]llegations in the complaint that are 'contradicted by more specific allegations or documentary evidence' are not entitled to a presumption of truthfulness." *MBIA Inc. v. Certain Underwriters at Lloyd's*, 33 F. Supp. 3d 344, 353 (S.D.N.Y. 2014) (quoting *Kirkendall v. Halliburton,* Inc., 707 F.3d 173, 175 n.1 (2d Cir. 2013)).

ARGUMENT

MEDTRONIC FAILS TO STATE A CLAIM UNDER RULE 12(b)(6)

When viewed in light of the proper construction of the Agreement's terms, the facts pled in Medtronic's Complaint do not support a claim for breach of contract – rather, its factual concessions prove just the opposite to be true.

New York law governs the interpretation of the Agreement. Agreement at 40. Basic rules of contract interpretation require that "words and phrases should be given their plain meaning, and a contract should be construed as to give full meaning and effect to all of its provisions."

Orchard Hill Master Fund Ltd. V. SBA Commc'ns Corp., 830 F.3d 152, 157 (2d Cir. 2016); *Cap. Access Servs. Inc. v. Direct Source Seafood LLC*, No. 17-CV-1405 (VSB), 2018 WL 3093967, at *4 (S.D.N.Y. June 22, 2018) (holding that in construing a contract, a court should give the words and phrases their plain meaning). Where, as here, a contract's language is clear and unambiguous, a court may dismiss a breach of contract claim on a Rule 12(b)(6) motion to dismiss. *See Maniolos v. United States*, 741 F. Supp. 2d 555, 567 (S.D.N.Y. 2010), *aff'd* 469 F. App'x 56 (2d Cir. 2012); *Millennium Partners, L.P. v. U.S. Bank Nat. Ass'n*, No. 12 CIV. 7581 HB, 2013 WL 1655990, at *2 (S.D.N.Y. Apr. 17, 2013) (dismissing breach of contract claim where language unambiguous).

In this one count Complaint, Medtronic alleges that Biogen breached the Agreement because it failed to pay Medtronic [redacted] in milestone payments pursuant to Section 6.1, and another [redacted] in invoiced amounts. These claims are incompatible with the clear and unambiguous terms of the Agreement and Medtronic's own factual concessions. For the reasons that follow, Medtronic's claim fails as a matter of law and should be dismissed with prejudice in its entirety.

A. Biogen Owes Medtronic Nothing More Under Section 11.6.4 For Payments Pursuant To Section 6.1.

The plain and unambiguous language of Section 11.6.4 requires that Biogen pay Medtronic at least [redacted] "pursuant to Section 6.1." Agreement at 35. It has already done so, and nothing more is owed.

1. Biogen Paid Medtronic Over [redacted] Pursuant To Section 6.1.

As detailed above, Biogen's payment obligations under Section 6.1 compensate for activities in the Pre-Clinical Stage, as described in Section 3.1 and budgeted in Workplan 1(a). The parties never got past the Pre-Clinical Stage prior to termination of the Agreement. As such,

all payments made by Biogen – which Medtronic concedes exceeded the [redacted] floor set by Section 11.6.4 – were "pursuant to Section 6.1."

Nonsensically, Medtronic argues that all non-milestone payments made by Biogen were made pursuant to Section 6.2, not Section 6.1. However, as set out above, Section 6.2 by its very terms obligates Biogen to pay for activities done pursuant to Section 3.2 (the Clinical Stage of work), not Section 3.1 (the Pre-Clinical Stage, and the only stage reached by the parties prior to termination). Medtronic's argument ignores inclusion in Workplan 1(a) of non-milestone budgeted amounts for the Pre-Clinical Stage clinical and regulatory work described in Section 3.1 (and thus compensated under Section 6.1).

Medtronic fails to allege any facts to support its conclusory statement that payments "by Biogen to Medtronic other than the [redacted] for Development Milestones 1-7 of the pre-clinical Development Plan were for Clinical Activities and Regulatory Activities under Section 6.2 and as set forth in . . . Workplan 1." Compl. ¶ 19. The Court is not required to accept such bare, conclusory allegations as true in deciding this motion, particularly where they are contradicted by other key concessions as set forth above. *Iqbal,* 556 U.S. at 678*; Edwards v. Sequoia Fund, Inc.*, 938 F.3d 8, 12 (2d Cir. 2019); *Ashland Glob. Holdings Inc. v. Valvoline, Inc.,* No. 21-CV-00498 (RA), 2022 WL 219997, at *4 (S.D.N.Y. Jan. 25, 2022).

Even if not conclusory, as discussed in detail above, these allegations directly contradict the plain and unambiguous language of the Agreement, rendering them without merit. *See Oppenheimer & Co., Inc. v. Trans Energy, Inc.*, 946 F. Supp. 2d 343, 351 (S.D.N.Y. 2013) (motion to dismiss granted in part where plaintiff's argument was "contradicted by the plain language of the contract."); *Condit v. Bedford Cent. Sch. Dist.,* 16-cv-6566-CS, 2017 WL 4685546, at *1 n.2 (S.D.N.Y. Oct. 16, 2017) (holding that the court "need not take as true any

allegations regarding the contents of the letter [referenced in the complaint] that are contradicted by the actual letter").

2. Medtronic Cannot Rewrite Section 11.6.4 To Impose A Floor On Milestones.

Medtronic tellingly mischaracterizes Section 11.6.4 as requiring Biogen to ensure Medtronic was paid [redacted] in the aggregate for "pre-clinical Development *Milestone* activities." Compl. ¶ 12. But the word "Milestone" does not appear anywhere in Section 11.6.4 (nor in Section 6.1 itself, which is referred to by Section 11.6.4). Rather, Section 11.6.4 requires Biogen to pay [redacted] in the aggregate "pursuant to Section 6.1" without qualification or limitation. Thus, any payment Biogen made for activities compensated under Section 6.1 (which are for pre-clinical activities described in Section 3.1 and budgeted in Workplan 1(a)), is credited toward the [redacted] aggregate. Had the parties intended to set a floor on Biogen's milestone payment obligations under Section 6.1, they could have included such language in the Agreement. They did not, and the Court should not permit Medtronic to rewrite the Agreement now to support claims for more than it bargained for. *Ashwood Cap., Inc. v. OTG Mgmt., Inc.*, 948 N.Y.S.2d 292, 297 (N.Y. App. Div. 2012) (A court "may not by construction add . . . terms, not distort the meaning of those used . . . under the guise of interpreting the writing.")

B. Biogen Is Not Obligated To Pay Medtronic's Invoices Which Are Not In Accordance With the Approved Development Plan Budget.

Medtronic's arguments concerning the January to June 2022 invoices again ignore explicit and clear language of the Agreement.

1. No Payments Are Owed Under Section 6.2.

Medtronic alleges that it is owed payment of such invoices under Section 6.2. As discussed in Section A.1. *supra*, Section 6.2 governs Biogen's payment obligations for the

Clinical Stage which was never reached. As such, no amounts are or were ever owing under Section 6.2.

2. No Payments Are Owed For Non-budgeted Invoices.

Under both Sections 6.1 and 6.2, Biogen's payment obligations apply only to amounts "in accordance with the budget for such activities as set forth in the Development Plan." Agreement at 19. By Medtronic's own concession, Biogen already paid amounts exceeding those shown in the Development Plan budget attached to the Agreement, thereby relieving Biogen of its obligation to pay for any further excesses. Compl. ¶¶ 38, 43. None of the invoiced amounts in dispute, therefore, could be supported by that Development Plan budget.[4]

Medtronic argues that the Development Plan budget attached to the Agreement did not act to limit Biogen's payment obligations, ignoring the plain meaning of – and rendering meaningless – the phrase "in accordance with the budget for such activities as set forth in the Development Plan." Such a result would contravene New York law. *See Orchard Hill Master Fund Ltd. V. SBA Commc'ns Corp.,* 830 F.3d 152, 156–57 (2d Cir. 2016) ("A contract should be construed so as to give full meaning and effect to all of its provisions."); *Cap. Access Servs. Inc. v. Direct Source Seafood, LLC*, No. 17-CV-1405 (VSB), 2018 WL 3093967, at *4 (S.D.N.Y. June 22, 2018), *aff'd*, 767 F. App'x 157 (2d Cir. 2019) quoting *Orchard Hill Master Fund,* 830 F.3d at 157 ("The basic rules of contract interpretation require that 'words and phrases should be given

[4] Medtronic references Biogen's use of a 2022 Medtronic forecast in Biogen's annual planning process. However, Medtronic does not – because it cannot – assert that Medtronic's forecast, or Biogen's use thereof, constituted a written amendment of the Agreement or formal approval of the Development Plan and budget therein. The facts are quite to the contrary – Biogen continued requests for Medtronic to submit and formalize and updated Development Plan; Medtronic chose not to do so at its own risk.

their plain meaning and a contract should be construed as to give full meaning and effect to all of its provisions.'")[5]

3. Biogen Neither Amended the Agreement's Terms, Nor Waived Its Rights To Limit Its Payment Obligations To Approved Budgeted Amounts.

Medtronic next alleges that the parties modified the terms of the Agreement by their course of performance, and/or that Biogen waived any such limitation on its payment obligations. Compl. ¶ 37. These theories of liability disregard express prohibitions on oral modifications in the Agreement, and fail as a matter of law.

Medtronic claims entitlement to payments beyond the approved budgets provided for in the Agreement because "the parties amended the Agreement by their course of performance," stating "Biogen waived any such limitation, and Biogen is estopped from asserting such limitation." *Id*. These allegations ignore two critical provisions in the Agreement that prohibit amendments and waivers not formalized in writing.

As discussed above, Section 14.8 of the Agreement states that "[a]ny term of this agreement may be amended only with the written consent of Biogen and Medtronic." Agreement at 41. Similarly, Section 14.10 prohibits any arguments of waiver where the alleged waiver was not specifically formalized in writing by the parties, and negates use of any delay or omission to exercise a party's rights to constitute waiver. *Id.* at 42. New York law requires strict enforcement of such provisions. *See Holahan v 488 Performance Group, Inc.,* 33 NYS.3d 214, 216 (N.Y. App. Div. 2016) (affirming dismissal of complaint where any agreement required

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[5] The requirement for alignment on budget to support Biogen's payment obligations extends to April-June 2022 invoices. Medtronic fails to mention that Biogen paid Medtronic's non-cancellable costs – those are not at issue in this dispute. Biogen has refused to pay for the April-June 2022 invoiced work for the same reasons set out above with respect to earlier invoiced amounts – without an agreed budget, Biogen has no payment obligations under the Agreement.

modification to be in writing); *Netto v. Rastegar*, No. 12 CIV. 4580 CM, 2012 WL 4336167, at *7 (S.D.N.Y. Sept. 20, 2012) (granting motion to dismiss because oral promise was insufficient to modify an agreement that requiring modification to be in writing); *Shetty v. SG Blocks, Inc.*, No. 20-CV-00550-ARR-SMG, 2020 WL 4719755, at *5 (E.D.N.Y. Aug. 13, 2020) (same); *Excel Graphics Techs., Inc. v. CFG/AGSCB 75 Ninth Ave., L.L.C.,* 767 N.Y.S.2d 99, 103 (N.Y. App. Div. 2003) (holding that there was no waiver as a matter of law because non-waiver provision specifically addressed scenario where one party deviates from the terms of the agreement and the other party delays or fails to object); *Five Star Elec. Corp. v. Silverite Constr. Co. Inc.*, 76 Misc. 3d 1213, 2022 N.Y. Slip Op. 50899(U), *5 (N.Y. Sup. Ct. 2022) (holding that there was no waiver as a matter of law under the agreement at issue because non-waiver clause provided "[t]he failure of either party hereto to insist, in any one or more instances, upon the performance of any of the terms, covenants or conditions of this Agreement, or to exercise any right herein, shall not be construed as a waiver or relinquishment of such term, covenant, condition or right."); *Colonia Ins., A.G. v. D.B.G. Prop. Corp.,* No. 89 CIV. 8640 (RPP), 1993 WL 100221, at *2 (S.D.N.Y. Mar. 29, 1993) (holding that there was no waiver as a matter of law because agreement stated that "[t]he failure of [the parties] to enforce any of the terms, covenants and provisions of this agreement shall not be deemed to be a waiver thereof."). Here, Medtronic has not alleged any written consent by Biogen to amend the Agreement, nor any written waiver by Biogen of the limitation on its payment obligations, nor could it as none exist.

While Medtronic alleges that Biogen waived through its course of conduct in accepting Medtronic's work when it knew that Medtronic was over budget, this type of waiver is exactly what Section 14.10 prohibits. Further, under New York law "[a]waiver must be "clear,

unequivocal and deliberate" *Silverman v. Silverman,* 756 N.Y.S.2d 14, 19 (N.Y. App. Div. 2003). Medtronic has alleged no such facts.

Sections 14.8 and 14.10 bar any argument that Biogen owes further payment over and above the budget excesses it has already paid based on non-written agreements to waive or amend the Agreement's requirements.

CONCLUSION

The Court should grant Biogen's Motion to Dismiss the Complaint in its entirety with prejudice for the reasons stated herein.

Dated: New York, New York
December 11, 2023

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